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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,967	09/13/2005	Charlotta All-Ericsson	ON/4-32739A	4092

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EXAMINER	
ROYDS, LESLIE A	
ART UNIT	PAPER NUMBER
1614	
MAIL DATE	DELIVERY MODE
12/08/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/531,967	ALL-ERICSSON ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 4-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-2 and 4-7 are presented for examination.

Applicant's Amendment filed July 24, 2009 has been received and entered into the present application.

Claims 1-2 and 4-7 remain pending and under examination. Claim 1 is amended.

Applicant's arguments, filed July 24, 2009, have been fully considered. Rejections not reiterated from previous Office Actions are hereby withdrawn. The following rejections are either reiterated or newly applied. They constitute the complete set of rejections presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2 and 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zimmerman et al. (WO 99/03854; 1999) in light of Mouriaux et al. ("Implication of Stem Cell Factor in the Proliferation

of Choroidal Melanocytes", *Exp. Eye Res.*, 2001; 73:151-157), cited as evidence, in view of Ijland et al. ("Expression of Angiogenic and Immunosuppressive Factors by Uveal Melanoma Cell Lines", *Melanoma Research*, 1999; 9:445-450), each already of record, for the reasons of record set forth at p.6-11 of the previous Office Action dated April 22, 2009, of which said reasons are herein incorporated by reference.

Response to Applicant's Arguments

Applicant traverses the instant rejection, stating that Zimmerman et al. teaches the crystal salt form of the claimed benzamide compound and alleges that the disclosure of Zimmerman et al. is clearly limited to the use of the crystal form to treat a broad range of proliferative, and preferably tumorous, diseases. Applicant opines Zimmerman et al. does not teach the treatment of uveal melanoma and asserts that, although Ijland et al. teaches that some uveal melanoma cell lines secrete VEGF, the secretion of VEGF is not specific to uveal melanoma and is common to many tumorous and proliferative diseases requiring neovascularization. Applicant alleges that an inhibitor of VEGF cannot necessarily effectively treat cancer cells excreting VEGF and relies upon the fact that the instantly claimed compound is ineffective in the treatment of skin melanoma cells (which Applicant asserts are "closely related to other melanomas"; p.5, Remarks).

Applicant's traversal has been fully and carefully considered, but fails to be persuasive.

Firstly, Applicant's characterization of Zimmerman et al. as being limited to the crystal salt form of the claimed benzamide compound for the treatment of a broad range of proliferative diseases, but not teaching the treatment of uveal melanoma, is unpersuasive. Zimmerman et al. provides a clear teaching to one of ordinary skill in the art that the instantly claimed compound is an effective inhibitor of the angiogenic effect of VEGF (and, thus, would have been functional to inhibit this same angiogenic effect of VEGF expression in therapeutic uses wherein inhibition of VEGF expression is desirable). These facts, coupled with the teaching of Ijland et al. that six different human primary uveal melanoma cell lines (92-

1, Mel-202, OCM-1, OCM-3, OCM-8 and EOM-3) are each known to demonstrate significant VEGF secretion, which is known to be indicative of angiogenic potency and vessel proliferation for neovascularization, clearly support the *prima facie* obviousness of the instantly claimed invention because one of ordinary skill in the art at the time of the invention would have been clearly motivated to use a compound that clearly inhibits angiogenesis associated with VEGF for treating a disease that clearly exhibits angiogenesis as a result of significant VEGF secretion. Such a person would have had a clearly reasonable expectation of success in treating uveal melanoma with such a compound because the inhibition of angiogenesis caused by VEGF expression would have inhibited the neovascularization necessary for tumor growth. The fact that Zimmerman et al. alone does not explicitly disclose the use of the instantly claimed compound for the treatment of uveal melanoma is irrelevant because the finding of obviousness was clearly based upon the teachings of Zimmerman et al. taken in combination with Ijland et al. Consideration of each reference individually without addressing how they were combined is, and will remain, unpersuasive.

Secondly, Applicant argues that the secretion of VEGF is not specific to uveal melanoma and is common to many tumorous and proliferative diseases requiring neovascularization. The intent of this argument is not clear. It may very well be that VEGF secretion is found in other tumorous and proliferative diseases requiring neovascularization, but this has no bearing on the determination of obviousness in the instant case, which is that uveal melanomas are known to demonstrate significant VEGF secretion for the purpose of neovascularization and the instantly claimed benzamide compound is known in the art to be an inhibitor of VEGF and, thus, one of skill in the art would have employed this same compound for the purpose of treating uveal melanoma by inhibiting its neovascularization ability necessary for tumor growth. Accordingly, this statement about VEGF being common to other proliferative diseases appears to drift away from the issues in the instant case and is, thus, clearly unpersuasive.

Thirdly, and lastly, Applicant alleges that an inhibitor of VEGF cannot necessarily effectively treat cancer cells excreting VEGF and relies upon the fact that the instantly claimed compound is ineffective in the treatment of skin melanoma cells (which Applicant asserts are "closely related to other melanomas"; p.5, Remarks) in support of his position. This is unpersuasive. Applicant is attempting to assert that a VEGF inhibitor is not necessarily effective in treating cancer cells with VEGF overexpression by citing an experiment presented in the instant application wherein the instantly claimed compound was ineffective in treating skin melanoma cells, but has conspicuously failed to set forth any evidence tending to show that skin melanoma cells, such as the ones studied in this experiment, *actually do, in fact, secrete VEGF*. There is no evidence or even reasoning of record to demonstrate that these same skin melanoma cells both secrete VEGF and are immune to the therapeutic effects of the instantly claimed compound to support his conclusion that the instantly claimed compound would not have been expected to be effective in treating all cancers known to secrete VEGF. Applicant is attempting to draw a conclusion that a VEGF inhibitor is not necessarily effective in treating cancer cells that secrete VEGF by relying upon an experiment using a distinctly different type of cancer cell that is not even disclosed as one that secretes VEGF. Accordingly, this is clearly not a proper scientific comparison and, thus, conclusions drawn therefrom are properly found unpersuasive in this regard.

In view of the foregoing, the evidence and reasoning provided to support nonobviousness does not outweigh the evidence and facts provided to support obviousness. As a result, the rejection is maintained.

For these reasons *supra*, and those previously made of record at p.6-11 of the Office Action dated April 22, 2009, rejection of claims 1-2 and 4-7 is proper.

Conclusion

Rejection of claims 1-2 and 4-7 is proper.

No claims of the present application are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds/
Patent Examiner, Art Unit 1614

December 2, 2009

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614